

## REMARKS

In the Office Action issued on December 22, 2006, the Examiner:

- characterized the application as described three patentably distinct species and required election of one species for prosecution on the merits;
- rejected Claims 9 through 11 under the second paragraph of 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention;
- rejected Claims 9 through 11 under 35 U.S.C. §101 as being directed to non-statutory subject matter;
- rejected Claims 1 through 4, 7 through 9, and 13 under 35 U.S.C. §102(b) as being anticipated by Duran (United States Patent No. 7,125,418);
- rejected Claims 1, 2 and 7 through 9 under 35 U.S.C. §102(b) as being anticipated by Moll (United States Patent No. 6,287,334);
- rejected Claims 5, 6, 10, 11, 14, and 15 under 35 U.S.C. §103(a) as being unpatentably obvious over Duran; and
- rejected Claims 3 through 6, 10, 11, and 13 through 15 under 35 U.S.C. §103(a) as being unpatentably obvious over Moll.

The Applicants have fully considered the Office Action and cited references and submit this Reply and Amendment in response to the Examiner's rejections. Reconsideration of the application for patent is requested.

### Response to Election Requirement

In the Office action, the Examiner asserted that the claims as filed are drawn to the following three (3) patentably distinct species:

Species 1: disclosed on pg. 16, lines 8-10, opening defined between leaflet edge and frame generally seen in figs. 4-6, 8, 9, and 13-15

Species 2: disclosed on pg. 17, lines 8-12, opening defined entirely by leaflet, seen generally in figs. 7, 10, 11, 12, 17A-17D, 20A-20D, and 21-23

Species 3: disclosed on pg.20, lines 18-31, opening defined by a flap, seen generally in figs. 18 and 19A-19F.

The Examiner states that "[t]he species are independent or distinct because they define structurally different types of openings (frame opening, leaflet hole,

leaflet flap) that all perform the same function, allowing retrograde flow.”

As indicated in the Office action, the Applicants have provisionally elected, with traverse, to prosecute the invention characterized as Species 1. The applicants hereby affirm this election.

The applicants acknowledge that Claims 1 through 11 and 13 through 15 are, because of the election, currently under examination and that Claims 12 and 16 through 28 have been withdrawn from further consideration at this time.

Applicants make the election of Species 1 without prejudice or disclaimer. Further, applicants reserve the right to resubmit claims directed to the non-elected species, including, but not limited to, the withdrawn claims, either through rejoinder practice or otherwise.

Applicants believe this Reply to be fully responsive to the election requirement issued by the Examiner. If, however, the Examiner believes that additional communication is necessary, Applicants respectfully request that she contact the attorney listed below.

#### **Rejection of Claims 9 through 11 under 35 U.S.C. §112, second paragraph**

The Examiner rejected Claims 9 through 11 under the second paragraph of 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner indicated that the limitation “the total open area” in line 1 of each claim has insufficient antecedent basis.

The applicants have herein amended each of Claims 9 through 11 to indicate that the opening has “a total open area” prior to the reference to “the total open area” solely to provide antecedent basis for a limitation that was already present in these claims. Neither the scope of the invention defined by these claims, nor the protection sought, have been narrowed by these amendments.

The amendments made to Claims 9 through 11 are fully supported by the specification as originally filed. For example, see the discussion of the size of the opening in the paragraph beginning on page 14, line 22 and continuing onto page 15. Furthermore, the term “total open area” is clearly defined on p.15, lines 6 through 9 of the specification as filed. No new matter has been introduced by these amendments.

#### **Rejection of Claims 9 through 11 under 35 U.S.C. §101**

The Examiner rejected Claims 9 through 11 under 35 U.S.C. §101 as being drawn to non-statutory subject matter. Specifically, the Examiner indicated that:

"[c]laiming a comparison to a portion of the body is non-statutory subject matter. Claims 9-11 each recite, "opening is less than...of the cross-sectional area of said body vessel." Applicant has compared the device directly to the body vessel."

The applicants respectfully traverse this rejection of the claims at least because the Examiner has not pointed to any controlling legal authority that supports it.

The question of whether a claim is directed to statutory subject matter is a question of law. See Arrhythmia Research Technology, Inc. v. Corazonix Corp., 958 F.2d (Fed. Cir. 1992). While it is true that there are qualifications on the general rule that Congress intended Section 101 of the Patent Act to include "anything under the sun made by man" Diamond v. Chakrabarty, 447 U.S. 303 (1980), the applicants are not aware of any authority that renders a claim violative of Section 101 simply because the claim includes a reference to a body portion. In the absence of a reference to such authority by the Examiner, which has not been provided to date, the applicants maintain that Claims 9 through 11 are fairly drawn to statutory subject matter.

Reconsideration of the rejection of Claims 9 through 11 is respectfully requested. If, upon reconsideration, the Examiner is unable to cite any controlling authority on this question of law, the applicants respectfully request that the Examiner remove the rejection.

#### **Rejection of Claims 1 through 4, 7 through 9, and 13 under 35 U.S.C. §102(e)**

The Examiner rejected Claims 1 through 4, 7 through 9, and 13 as being anticipated under 35 U.S.C. §102(e) by Duran.

The Applicants have herein amended independent claims 1 and 13 to clarify that the opening "permits a controlled amount of fluid flow to pass through said medical device in the second, opposite direction."

Duran fails to disclose this requirement of Claims 1 and 13 and, therefore, cannot anticipate these claims under 35 U.S.C. §102. Referring to the Examiner's markup of Duran, included in the Office action as Attachment 1, the opening referred to by the examiner would only permit fluid flow to enter the space between the outer surface of the valve body and the wall of the collapsible support system in which it *must be attached* (see, e.g., c. 5, lines 11 through 18). Flow *through the medical device* disclosed in Duran is precluded by the circular support 17, which is secured to the interior of the support system (see, e.g. Figure 9).

Applicants respectfully assert that Duran fails as an anticipatory reference for independent Claims 1 and 13 at least because it fails to disclose the limitation, that the opening “permits a controlled amount of fluid flow to pass through said medical device in the second, opposite direction.” Each of Claims 2 through 4 and 7 through 9 ultimately depend from independent Claim 1 and, therefore, also include this limitation. As a result, Duran also fails to anticipate these claims.

At least for this reason, the rejection of Claims 1 through 4, 7 through 9, and 13 as being anticipated under 35 U.S.C. §102(e) by Duran is improper. Applicants respectfully request withdrawal of this rejection of the claims.

### **Rejection of Claims 1, 2 and 7 through 9 under 35 U.S.C §102(b)**

The Examiner rejected Claims 1, 2, and 7 through 9 as being anticipated under 35 U.S.C. §102(b) by Moll.

The Applicants have herein amended independent claims 1 and 13 to clarify that the opening “permits a controlled amount of fluid flow to pass through said medical device in the second, opposite direction.”

Moll fails to disclose this requirement of Claims 1 and 13 and, therefore, cannot anticipate these claims under 35 U.S.C. §102. Referring to the Examiner's markup of Moll, included in the Office action as Attachment 2, the opening referred to by the examiner (near element 16) would only permit fluid flow to *enter* the space between the inner 12 and outer 14 walls (best illustrated in Figure 1). The opening would not permit fluid flow *to pass through* the medical device. Indeed, Moll explicitly describes the disclosed device as *preventing* such flow through the medical device upon entering this space:

“In this way between heartbeats, which force the blood through the venal system, any blood flowing in the opposite direction to the blood stream opens the proximal end of the stoppage element thereby forcing the sidewalls apart to enter the temporary blood storage area, *instead of passing through the device to leak back into the blood vessel in the direction from where it has just been pumped*. Since opening of the blood flow stoppage element effectively closes off the blood vessel, a very effective valve is provided.” (Moll, c.1, line 65 through c.2, line 7) (emphasis added).

Applicants respectfully assert that Moll fails as an anticipatory reference for independent Claims 1 and 13 at least because it fails to disclose the limitation that the opening “permits a controlled amount of fluid flow to pass through said medical device in the second, opposite direction.” Each of Claims 2 and 7 through 9 ultimately depend from independent Claim 1 and, therefore, also

include this limitation. As a result, Moll also fails to anticipate these claims.

At least for this reason, the rejection of Claims 1, 2, and 7 through 9 as being anticipated under 35 U.S.C. §102(b) by Moll is improper. Applicants respectfully request withdrawal of this rejection of the claims.

#### **Rejection of Claims 5, 6, 10, 11, 14, and 15 under 35 U.S.C. §103(a).**

The Examiner rejected Claims 5, 6, 10, 11, 14, and 15 under 35 U.S.C. §103(a) as being unpatentably obvious over Duran.

Applicants respectfully that the Examiner's rejection is rendered moot by the amendment made to Claims 1 and 13 herein. Furthermore, Applicant asserts that the the Examiner has failed to establish a *prima facie* case of obviousness for the rejected claims, each of which include this limitation.

To serve as a *prima facie* case of obviousness, a reference or combination of references must satisfy three criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. M.P.E.P §2143.

As detailed above, Duran fails to teach or suggest the limitation that the opening "permits a controlled amount of fluid flow to pass through said medical device in the second, opposite direction." Each of the rejected claims includes this limitation. Accordingly, Duran fails to establish a *prima facie* case of obviousness for each of the rejected claims at least because of its failure to teach or suggest this limitation.

At least for this reason, the rejection of Claims 5, 6, 10, 11, 14, and 15 under 35 U.S.C. §103(a) as being unpatentably obvious over Duran is improper. Applicants respectfully request withdrawal of this rejection of the claims.

#### **Rejection of Claims 3 through 6, 10, 11, and 13 through 15 under 35 U.S.C. §103(a).**

The Examiner rejected Claims 3 through 6, 10, 11, and 13 through 15 under 35 U.S.C. §103(a) as being unpatentably obvious over Moll.

Applicants respectfully that the Examiner's rejection is rendered moot by the amendment made to Claims 1 and 13 herein. Furthermore, Applicant asserts that the the Examiner has failed to establish a *prima facie* case of obviousness for the rejected claims, each of which include this limitation.

To serve as a *prima facie* case of obviousness, a reference or combination of references must satisfy three criteria. First, there must be some suggestion or

motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. M.P.E.P §2143.

As detailed above, Moll fails to teach or suggest the limitation that the opening “permits a controlled amount of fluid flow to pass through said medical device in the second, opposite direction.” Each of the rejected claims includes this limitation. Accordingly, Moll fails to establish a *prima facie* case of obviousness for each of the rejected claims at least because of its failure to teach or suggest this limitation.

Indeed, Moll specifically teaches away from the inclusion of an opening that “permits a controlled amount of fluid flow to pass through said medical device in the second, opposite direction.” As described in Moll:

“In this way between heartbeats, which force the blood through the venal system, any blood flowing in the opposite direction to the blood stream opens the proximal end of the stoppage element thereby forcing the sidewalls apart to enter the temporary blood storage area, *instead of passing through the device to leak back into the blood vessel in the direction from where it has just been pumped*. Since opening of the blood flow stoppage element effectively closes off the blood vessel, a very effective valve is provided.” (Moll, c.1, line 65 through c.2, line 7) (emphasis added).

At least for this reason, the rejection of Claims 3 through 6, 10, 11, and 13 through 15 under 35 U.S.C. §103(a) as being unpatentably obvious over Moll is improper. Applicants respectfully request withdrawal of this rejection of the claims.

## CONCLUSION

The Applicants have fully responded to the rejections listed by the Examiner in the December 22, 2006 Office Action. Applicants respectfully assert that all pending claims define patentable subject matter and request their reconsideration and issuance of an appropriate Notice of Allowability.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,

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